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EXAMINER	
SIGLER, JAY R	

ART UNIT	PAPER NUMBER
4111	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/561,509	CLEMENT ET AL.	
	Examiner	Art Unit	
	JAY R. SIGLER	4111	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 April 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 December 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *20 December 2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Priority

1. Acknowledgment is made of applicant's claim for foreign priority based on applications filed in France on 27 June 2003, 27 January 2004, and 01 April 2004, 03/07776, 04/00747, and 04/03413, respectively. It is noted, however, that applicant has not filed a certified copy of these applications as required by 35 U.S.C. 119(b).

Claim Objections

2. Claim 1 is objected to because of the following informalities: the term "i.e." should be replaced with --wherein-- for clarity. Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 5 recites the limitation "elastically deformable structure" in line 8. There is insufficient antecedent basis for this limitation in the claim. The claim is dependent on claim 1 which does not claim the elastically deformable structure. This structure is claimed in claim 2. Claim 5 will be considered to be dependent on claim 2 and therefore the limitation of the elastically deformable structure will be considered as part of the invention of claim 5 for further examination.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1 and 11 are rejected under 35 U.S.C. 102(e) as being anticipated by Rivard et al. (US 6,554,831).

a. Claim 1: Rivard et al. teaches **vertebral osteosynthesis equipment, including bony anchoring members, such as pedicular screws** (20), **two linking rods** (12 and 14), **intended to be connected to these anchoring members, and parts** (16a and 16b) **for connecting these rods to these anchoring members; at least one of the anchoring members is of the "polyaxial" type** (embodied by the ball joint shown in Fig. 2, col. 4, ll. 11-16), **i.e. it comprises a proximal stud** (30) **articulated with respect to a base portion** (upper part of 20) **enabling bony anchoring; clamping means** (40) **enable assembly of the connecting part on the anchoring member; equipment characterized in that the proximal stud comprises a surface** (36) **forming an axial stop, against which the connecting part to be installed on the polyaxial anchoring member is intended for resting** (shown in Fig. 2), **and in that said clamping means enable to clamp this connecting part against this surface, said surface being positioned so that the connecting part, when it is clamped against this surface, is not clamped against the base portion so that there remains, after clamping, a possibility of articulated backlash of**

the proximal stud with respect to said base portion (embodied by Fig. 2, col. 4, ll.25-30).

b. Claim 11: the connecting part comprises a rounded section 23 and two parallel drilled wings (24 and 26).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 2-4 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rivard et al. (US 6,554,831) as applied to claim 1 above, and further in view of Lahille et al. (US 5,380,325).

c. Claim 2: Rivard et al. teaches the claimed invention, but does not specifically teach including an elastically deformable structure. Lahille et al. suggests vertebral osteosynthesis equipment including an elastically deformable structure 25 interposed between a connecting part 3 and a bearing surface 23 in order to dampen and thus cancel damaging movements to the rod or screws that could cause cracks or breaks (col. 5, l. 68 to col. 6, l. 4). It would have been obvious to one of ordinary skill in the art at the time of the invention to include an elastically deformable structure, such as suggested by Lahille et al., in the invention of Rivard et al. in order to dampen and thus cancel damaging movements to the rod or screws that could cause cracks or breaks.

d. Claims 3: the elastically deformable structure of Lahille et al. is a compressible material and would dampen movement over the whole backlash of the stud considering it encircles the stud.

e. Claim 4: the claim is unpatentable because it has been held that where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

f. Claim 7: Lahille et al. suggests the elastically deformable structure resting on the bearing surface.

9. Claims 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rivard et al. (US 6,554,831) in view of Lahille et al. (US 5,380,325) as applied to claim 2 above, and further in view of Mirkovic (US 5,254,118).

g. Claim 5: Rivard et al., in view of Lahille et al., suggests the claimed invention including having a elastically deformable structure, but does not suggest that the axial stop and the proximal stud are formed to enable the adjustment of the axial position of the axial stop with respect to the proximal stud. It would naturally follow that this would in turn adjust the axial position of the connecting member with respect to proximal stud. Mirkovic suggests vertebral osteosynthesis equipment where the axial position of the connecting member 30 is adjustable on the proximal stud (embodied by top part of 14) and this is done using an axial stop (embodied by nut 38) which is also adjustable in order to position the rod properly (embodied by the Abstract). It would have been obvious

to one of ordinary skill in the art at the time of the invention to use an adjustable axial stop, such as suggested by Mirkovic, in the invention of Rivard et al., in view of Lahille et al., in order to position the rod properly. Additionally, the claim is unpatentable because it has been held that adjustability, where needed, is not a patentable advance, and because there was an art-recognized need for adjustment. *In re Stevens* , 212 F.2d 197, 101 USPQ 284 (CCPA 1954). Concerning the further limitation, an adjustable axial stop would be capable of clamping the elastically deformable structure to the bearing surface.

h. Claim 6: the proximal stud of Rivard et al. is threaded and adding a tapered hole to allow for an easier application of the axial stop onto the proximal stud would have been an obvious improvement in the art.

10. Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rivard et al. (US 6,554,831).

i. Claim 8: Rivard et al. teaches the claimed invention except for the implant including a ceramic or titanium nitride coating layer. However, ceramic or titanium nitride coating layers were art recognized for providing a smooth and resistant coating. It would have been obvious to one having ordinary skill in the art at the time the invention was made include ceramic or titanium nitride coating layers, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re *Leshin*, 125 USPQ 416.

j. Claim 9: Rivard et al. teaches the articulation of the proximal stud consists of spherical faces (46 and opposite face), but does not specifically teach that the diameter of the faces is double the diameter of the stud. The claim is unpatentable because it has been held that where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device. In *Gardner v. TEC Systems*, Inc., 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), *cert. denied*, 469 U.S. 830, 225 USPQ 232 (1984)

11. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rivard et al. (US 6,554,831) as applied to claim 1 above, and further in view of Fortin et al. (WO 03/007828). US 2005/0165396 is the national stage application of WO 03/007828 and is being relied on as a translation. The following references are drawn to US 2005/0165396. Rivard et al. teaches the claimed invention except for the special structure of the rod. Fortin et al. teaches a rod for use in vertebral osteosynthesis equipment that includes a portion with elastically deformable structure 122 and articulated stud 110, another portion of rod 16 including a bearing zone 114, and a clamping means 112 to allow the rod to provide both resistance and mechanical stress damping forces with the purpose of compensating for any deficiency in the flexibility of certain anatomical links of the human body. It would have been obvious to someone of ordinary skill in the art at the time of the invention to include the rod of Fortin et al. in the invention of Rivard et al. in order to allow the rod to provide both resistance and

mechanical stress damping forces with the purpose of compensating for any deficiency in the flexibility of certain anatomical links of the human body.

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 6,267,765 is considered particularly pertinent.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAY R. SIGLER whose telephone number is (571)270-3647. The examiner can normally be reached on Monday through Thursday from 8 AM to 4 PM (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sam Yao can be reached on (571) 272-1224. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JRS

/Sam Chuan C. Yao/
Supervisory Patent Examiner, Art Unit 4111